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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,975	07/14/2003	Mark D. Soll	MER 03-009	8586

33928 7590 08/22/2007

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EXAMINER	
PRYOR, ALTON NATHANIEL	
ART UNIT	**PAPER NUMBER**
1616	
MAIL DATE	**DELIVERY MODE**
08/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,975	SOLL ET AL.	
	Examiner	Art Unit	
	Alton N. Pryor	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-63* is/are pending in the application.

4a) Of the above claim(s) *3,4,8,9,11-13,15,16 and 18-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6,7,10,14 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/31/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, see paper, filed 5/20/07, with respect to the rejection(s) of claim(s) under 35 USC 103(a) as being obvious over Meinke et al (WO 9629073; 9/26/96) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made below.

I. Old Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2,6 not remain rejected under 35 U.S.C. 102(b) as being anticipated by Meinke et al (WO 9629073; 9/26/96) and Cleverly et al (USAN 2004/0037869; 2/26/04). Meinke teaches a formulation comprising the elected t-butyl nodulisporamide (where R3 = OH; R1 and R2 together is =O; R3,R4 = OH, R5 = H; and R7 = fragment having double bond with R10 being the t-butyl amide group) and liquid carriers such as propylene glycol. Meinke also teaches that the formulation can be formulated as a spot on formulation. However, whether the formulation is a spot on or an oral formulation does not matter since a statement of intended use in a claim to a formulation does not carrier patentable significance. See abstract, page 34 line 8 – page 37 line 23, claim 13.

Response to Applicants' Amendment

Applicants have amended claims to require "crystallization inhibitor". For this reason a new search was conducted and a new rejection is cited below.

II. New Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2,6,7,10,14,17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meinke et al (WO 9629073; 9/26/96) and Cleverly et al (USAN 2004/0037869; 2/26/04). Meinke teaches a formulation comprising the elected t-butyl nodulisporamide (where R3 = OH; R1 and R2 together is =O; R3,R4 = OH, R5 = H; and R7 = fragment having double bond with R10 being the t-butyl amide group) and liquid carriers such as propylene glycol. Meinke also teaches that the formulation can be formulated as a spot on formulation. However, whether the formulation is a spot on or an oral formulation does not matter since a statement of intended use in a claim to a formulation does not carrier patentable significance. See abstract, page 34 line 8 – page 37 line 23, claim 13. Meinke does not teach 1) an exemplification of the elected t-butyl Nodulisporamide, 2) the combination of the elected t-butyl nodulisporamide with propylene glycol as the carrier and a crystallization inhibitor in a composition. However, it would have been obvious to one having ordinary skill in the art to have made the

elected t-butyl nodulisporamide and combine it with propylene glycol to arrive at a formulation as claimed. One would have been motivated to make the elected t-butyl nodulisporamide compound since claim 13 of WO '073 suggests Rx as t-butyl. One would have been further motivate to combine the elected t-butyl nodulisporamide with propylene glycol since WO '073 at page 35 line 26 suggests the combination. With respect to the crystallization inhibitor Cleverly teaches a formulation that can contain numerous pharmaceutical agents including nodulisporic acid derivatives. See paragraph 62. Cleverly teaches that the formulation can be used as a pour-on formulation. See paragraph 175. Cleverly teaches that the formulation can further comprise benzyl alcohol (crystallization inhibitor) and / or polyoxyethylene sorbitan fatty acid esters (crystallization inhibitor). See paragraphs 186-187. It would have been obvious to one having ordinary skill in the to combine the prior art compositions since they are both nodulisporic acid derivatives such as nodulisporamide. Note applicant elects transcutol as the carrier for the elected t-butyl nodulisporamide. However, applicant does not show that transcutol would have provided a result different from that obtained using another structurally similar carrier. For this reason, Meinke makes the elected composition comprising t-butyl nodulisporamide and transcutol obvious.

Election Status

The elected invention comprising t-butyl nodulisporamide and transcutol is not allowable. See art rejection above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alton Pryor
Primary Examiner
AU 1616